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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/486,623 | 07/06/00 | NIELSEN | P ISIS-3292 |

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EXAMINER
MARSCHEL, A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1631 | 7 |

DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/486,623

Applicant(s)
Nielsen et al.

Examiner
Ardin Marschel

Art Unit
1631



- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-54 is/are pending in the application.
- 4a) ~~Claim(s) 1-22 have been canceled.~~ Claim(s) 1-22 have been canceled.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 23-54 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: **RAW SEQUENCE LISTING ERROR REPORT**

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because of errors as listed on the enclosed RAW SEQUENCE LISTING ERROR REPORT. Applicants must submit a new computer readable form, paper copy for the specification, and a statement under 37 CFR § 1.821(f). Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

This application has been filed under 35 U.S.C. § 371 and has been determined to have Lack of Unity of invention under PCT Rule 13.1 and under 37 CFR § 1.499 regarding the U.S. National Stage application as summarized below:

I. Claims 23-30, 39-44, and 54; drawn to methods of killing or inhibiting growth of bacteria, classified in Class 514, subclasses 2 and 44. If this Group is elected, then the below summarized specie elections A and B are also required.

II. Claims 31-38, drawn to processes for determining the

function of a target gene in a bacteria, classified in Class 435, subclass 6. If this Group is elected then the below summarized specie election A is also required.

III. Claims 45-53, drawn to antibacterial pharmaceutical compositions, classified in Class 530, subclass 300.

The inventions are distinct and lack a common Special Technical Feature, each from the other because of the following reasons:

Inventions of Group III and Groups I and II are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the PNA compositions of Group I may be utilized in assays as hybridization probes or alternatively, in the distinct usages of Groups I and II, each being a separate and non-overlapping usage of such PNA compositions. Alternatively, the compositions of Group III lack the specificity requirement of killing, inhibiting, disinfecting, or gene function determination of Groups I and II and thus are not directed to the same Special Technical Feature. The common presence of PNA compounds is only a portion of each Group and is not deemed to completely define the Special Technical Feature in each Group, but such Features

include those practices also for each Group as summarized in the preceding as well as following paragraphs.

The inventions of Groups I and II are separate and non-overlapping in that inhibition or killing or disinfecting of Group I lacks any result determination of the what actually inhibited etc. the bacterial target which is, however, the central issue in Group II with also a gene function determination which is also not needed for the Group I inhibition etc. Thus, Groups I and II are not directed to the same Special Technical Feature.

SPECIE ELECTIONS A AND B:

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: The location of PNA action as being in vivo or vitro define distinct species in that different considerations are required for delivery, half-life, activity, tolerance, etc. for each species.

Specie A-1: In-vivo PNA action, such as treatment in a mammal, for example

Group I claims - 23-30, 39-42, and 54

Group II claims - 31, 33, and 35-38

Specie A-2: In-vitro PNA action, such as bacterial inhibition, killing, or disinfection outside of a mammal, for example

Group I claims - 23-30, 43, and 44

Group II claims - 31, 32, and 34-38

Specie B: The presence or absence of additional antibiotic(s) over PNA presence are distinct species in that PNA alone versus PNA plus antibiotic(s) separately results in consideration of synergistic effects, competitive effects, each compound delivery efficiency, and separate side effects

Specie B-1: PNA alone without additional antibiotic(s)

Group I claims - 23-25, 27-29, 39-41, 43, 44, and 54

Specie B-2: PNA plus additional antibiotic(s) presence

Group I claims - 23-30, 39-44, and 54

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the following claims are generic to all species in their respective groups: Group I claims 23-25, and 27-29 and Group II claims 31 and 35-38.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

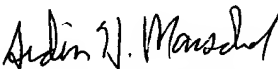
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703)308-0196.

September 7, 2001


ARDIN H. MARSCHEL
PRIMARY EXAMINER